

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Withdrawn claims 1 and 6-12 have been canceled, claims 2-3 have been amended, and claim 13 has been added. Accordingly, claims 2-5 and 13 are under examination in the application. Support for the above amendments can be found throughout the specification as originally filed. For example, support for the recitation of "naturally processed epitope" and "amino acid residues 975-1209 of human Her-2/neu" can be found in Example 2 of the specification as originally filed, at page 87, lines 7-25, wherein it is described that a naturally processed CD8+ epitope was found to be contained within a 235 amino acid fragment beginning at position 975 in the Her-2/neu sequence, said epitope having the amino acid sequence set forth in SEQ ID NO: 3. The above amendments are not to be construed as acquiescence to the stated grounds for objection/rejection and are made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Objections to the Specification & Claims

According to the Examiner, the Declaration supplied by Applicants is defective and a new Oath or Declaration in compliance with 37 C.F.R. § 1.67(a) is required in which the application is identified by its serial number and filing date. More particularly, the Examiner states that the Declaration is defective because it does not identify the mailing or post office address of each inventor. The Examiner further states that the mailing or post office address may be provided in an application data sheet (ADS) or a supplemental Oath or Declaration.

Applicants respectfully submit that the requirements noted by the Examiner were indeed satisfied by Applicants' submission of an Application Data Sheet (ADS) in accordance with 37 C.F.R. §§ 1.63(c) and 1.76. Enclosed for the Examiner's convenience is a copy of the ADS filed in the subject application on November 28, 2001, as well as the post card returned by the U.S.P.T.O. evidencing receipt of the ADS. Reconsideration of this objection is respectfully requested.

The Examiner also objects to the disclosure on the basis that the first paragraph of the specification requires amendment to reflect the status of the parent applications. Accordingly, Applicants have amended the first paragraph of the specification as requested.

In addition, the Examiner alleges that Applicants' specification requires correction in its use of "Tween 20™". More particularly, the Examiner requests that trademarks be capitalized and accompanied by generic terminology. In reply to this objection, Applicants have amended the specification by replacing each occurrence of "Tween 20™" with "TWEEN® 20 detergent".

The Examiner's objection to claim 3 for reciting non-elected limitations has been corrected.

#### Double Patenting Rejection

Claims 2 and 3 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 and 2 of U.S. Patent No. 6,075,122 ("the '122 patent"). According to the Examiner, although the claims are drawn to an isolated polypeptide effective to elicit an immune response, this limitation is viewed as a recitation of intended use and therefore is not given weight in comparing the claim with the patented case. The Examiner further states that although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept, and a polypeptide comprising an amino acid sequence of SEQ ID NO: 3 would have been obvious in view of the copending claims which allegedly have all of the characteristics as claimed.

Applicants respectfully traverse this rejection. As set forth by the above amendment, the currently claimed invention is drawn to an isolated polypeptide composition effective for eliciting an immune response, said polypeptide comprising the naturally processed Her-2/neu epitope of SEQ ID NO: 3 and said polypeptide consisting of no more than amino acid residues 975-1209 of human Her-2/neu. The '122 patent fails to disclose or render obvious this claimed invention as this cited art does not fairly teach or suggest each and every element of the claims. More specifically, the cited reference fails to disclose a Her-2/neu polypeptide fragment consisting of no more than amino acid residues 975-1209 of human Her-2/neu protein, fails to

disclose that such a polypeptide would possess the desired ability to elicit a CD8+ human T-cell response, as demonstrated by Applicants in Example 2, and also fails to disclose that an important epitope within this polypeptide that contributes to the desired CD8+ T-cell response occurs in Her-2/neu at residues 1021-1030, corresponding to the amino acid sequence set forth and claimed as SEQ ID NO: 3.

Applicant's claims to specific immunogenic fragments of Her-2/neu could not have been obvious to the skilled artisan absent some teaching or suggestion of the desirability of selecting a polypeptide having the recited structural limitations. However, such a teaching or suggestion is clearly absent from the prior art. Rather, it is only in view of Applicants' demonstration of the T-cell immunogenicity of a claimed Her-2/neu polypeptide that a skilled artisan would have found motivation for making a composition as currently claimed. Accordingly, as the '122 patent fails to teach, suggest or otherwise motivate a skilled artisan to make a Her-2/neu polypeptide composition having the specifically recited claim limitations, Applicants respectfully request reconsideration of the Examiner's rejection.

#### Novelty Rejection

Claims 2-5 stand rejected as being anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,057,122 ("the '122 patent"), and anticipated under 35 U.S.C. § 102(b) by the related U.S. Patent No. 5,801,005 ("the '005 patent"). Applicants note in this regard that the '122 patent issued from a continuation application of the application that issued as the '005 patent. According to the Examiner, the '122 and '005 patents teach SEQ ID NO: 69 (FIG. 1) which allegedly represents an isolated polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO: 3. Also according to the Examiner, the '122 and '005 patents describe that Her2/neu, which functions as an antigen, and include SEQ ID NO: 69, may be used for immunization in a composition that includes other components as a vehicle for antigen delivery and immunostimulatory substances designed to enhance the protein's immunogenicity.

Applicants respectfully traverse this rejection. As set forth by the above amendment, the currently claimed invention is drawn to an isolated polypeptide composition effective for eliciting an immune response, said polypeptide comprising the naturally processed Her-2/neu epitope of SEQ ID NO: 3 and said polypeptide consisting of no more than amino acid

residues 975-1209 of human Her-2/neu. Applicants respectfully submit that the '122 and '005 patents fail to anticipate this claimed invention as this cited art does not fairly teach or suggest each and every element of the claims. More specifically, the cited references fail to disclose a Her-2/neu polypeptide fragment consisting of no more than amino acid residues 975-1209 of human Her-2/neu protein, fail to disclose that such a polypeptide would possess the desired ability to elicit a CD8+ human T-cell response, as demonstrated by Applicants in Example 2, and also fail to disclose that an important epitope within this polypeptide that contributes to the desired CD8+ T-cell response occurs in Her-2/neu at residues 1021-1030, corresponding to the amino acid sequence set forth and claimed as SEQ ID NO: 3. Accordingly, as the '122 and '005 patents cited by the Examiner fail to disclose each and every element of the currently claimed invention, Applicants respectfully submit that the claimed invention is indeed novel over this cited art. Reconsideration of the Examiner's rejections is thus respectfully requested.

Obviousness Rejection

Claims 2-5 stand rejected as being obvious under 35 U.S.C. § 103 over Slamon *et al.* (Science, 1989, 244 (4905): 707-712) or Yamamoto *et al.* (Nature, 1986, 319: 230-234), or Coussens *et al.* (Science, 1985, 230: 1132-1139), in view of Harlow and Lane (Antibodies, A Laboratory Manual, 1988, Cold Spring Harbor Laboratory, New York) and Johnstone and Thorpe (Immunochemistry in Practice, 2<sup>nd</sup> Ed., 1987, Blackwell Scientific Publications, Oxford, pages 49-50).

According to the Examiner, Slamon *et al.*, Yamamoto *et al.* and Coussens *et al.* each teach an isolated Her2/neu polypeptide comprising an amino acid sequence consisting essentially of SEQ ID NO: 3 (pointing to FIG. 1, pg. 244; FIG. 4, pg. 233; and FIG. 3, pg. 1135, respectively), but do not teach a composition comprising said polypeptide, or a pharmaceutical composition for eliciting an immune response comprising said polypeptide. However, according to the Examiner, Harlow and Lane teach that adjuvants are essential to induce a strong antibody response to soluble antigens. Moreover, the Examiner asserts that Johnstone and Thorpe teach that it was common practice in the art to formulate compositions of proteins and pharmaceutically acceptable carriers, such as PBS. The Examiner concludes that it would have been prima facie obvious at the time the invention was made to have made a pharmaceutical

composition comprising the polypeptide of Slamon *et al.* or Coussens *et al.* or Yamamoto *et al.*, comprising an amino acid sequence consisting essentially of SEQ ID NO: 3, comprising a pharmaceutically acceptable carrier, an immunostimulant or an adjuvant.

Applicants respectfully traverse this rejection. As set forth by the above amendment, the currently claimed invention is drawn to an isolated polypeptide composition effective for eliciting an immune response, said polypeptide comprising the naturally processed Her-2/neu epitope of SEQ ID NO: 3 and said polypeptide consisting of no more than amino acid residues 975-1209 of human Her-2/neu. Applicants respectfully submit that the cited combination of references fails to disclose or render obvious this claimed invention as this cited art, alone or in combination, does not fairly teach or suggest each and every element of the claims. More specifically, the cited reference fails to teach or suggest a Her-2/neu polypeptide fragment consisting of no more than amino acid residues 975-1209 of human Her-2/neu protein, fails to disclose that such a polypeptide would possess the desired ability to elicit a CD8+ human T-cell response, as demonstrated by Applicants in Example 2, and also fails to disclose that an important epitope within this polypeptide that contributes to the desired CD8+ T-cell response occurs in Her-2/neu at residues 1021-1030, corresponding to the amino acid sequence set forth and claimed as SEQ ID NO: 3.


Applicant's claims to specific immunogenic fragments of Her-2/neu could not have been obvious to the skilled artisan absent some teaching or suggestion of the desirability of selecting a polypeptide having the recited structural limitations. However, such a teaching or suggestion is clearly absent from the prior art. Rather, it is only in view of Applicants' demonstration of the T-cell immunogenicity of a claimed Her-2/neu polypeptide that a skilled artisan would have found motivation for making a composition according to the claims. Accordingly, as the cited art clearly fails to teach, suggest or otherwise motivate a skilled artisan to make a Her-2/neu polypeptide composition having the specifically recited limitations currently claimed, Applicants respectfully submit that the claimed invention is non-obvious and patentable over this cited art. Reconsideration is respectfully requested.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be in condition for allowance. Favorable consideration is respectfully requested.

Respectfully submitted,

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Enclosure:

Postcard

Copy of ADS sent 11/28/01

Copy of Postcard from Response to Missing Parts sent 11/28/01

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